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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/839,658	Applicant(s) BRADLEY ET AL.	
	Examiner Teresa E. Strzelecka	Art Unit 1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *02 June 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-14,17,67 and 68*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Applicants' arguments were not considered persuasive. Regarding the rejection of claims 1-6, 17, 67 and 68 over Kallioniemi et al. and McGill et al., Applicants argue the folowing:.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

TS 6/15/05

JEFFREY FREDMAN
PRIMARY EXAMINER
6/17/05

9.0-0

A) Secondary considerations, where Applicants' methods of using target labeled nucleic acids (= probes) of less than 200 bp "achieve unexpectedly superior CGI resolution and reduction in the amount of repetitive sequence hybridization and cross-hybridization from closely related sequences". Applicants cite specification page 23, lines 1-8, to support this position. However, there is no evidence in the specification that using probes shorter than 200 bp in CGH hybridization leads to such unexpected results. In fact, in Example 1, on pages 27 and 28, the probes prepared for hybridization to BAC arrays were prepared by nick translation of genomic DNA, which, according to the Kallioniemi et al. reference cited by Applicants in support of their arguments, results in average size of fragments between 600 and 2000 bp (page 235, fourth paragraph of Kallioniemi et al., 1994), and by labeling of a 10 kb and 1 Mb fragments, which are clearly nowhere near less than 200 bp. Therefore, Applicants presented no evidence that using probes shorter than 200 bp resulted in unexpected results.

B) There is no motivation to combine Kaliioniemi et al. and McGill et al., since Kallioniemi et al. teach methods of molecular profiling using arrays, whereas McGill et al. teach detection of gene amplification on chromosome 8. Applicants further argue unexpected results, which were addressed above. Applicants go on to argue that neither Kallioniemi et al. nor McGill et al. teach or suggest problems of aggregating hybridization or high background, which, according to Applicants, are solved using probes of the size claimed by Applicants. First, both Kallioniemi et al. and McGil et al. teach hybridization methods which involve large DNA targets, such as BACs, PACs or P1 vectors of Kallioniemi et al., which contain anywhere from 10 kb to 1Mb of genomic DNA, and whole chromosome 8 of McGill et al. Therefore, since McGill et al. teach using small probes for hybridization to a whole chromosome 8, it would have been obvious in view of their teachings to apply them to BAc arrays, for example. Further, it is not clear why either reference would need to teach or suggest problems of aggregating hybridization and high backgrounds, since these are not present as claim limitations.

C) Non-analogous art, in which Applicants argue that McGill et al. is not in the same field of invention as claims 1-6, 17, 67 and 68, since "Both McGill and the invention are drawn to comparative genomic hybridization (CGH) but not the same method of applying this technology. Whereas McGill teaches fluorescent in situ hybridization of metaphase spreads, the instant claims are drawn to a plurality of DNA molecules on an array. Simply because a reference is considered to be in the same industry as an invention does not necessarily mean that the reference is analogous art." Applicants further argue that the methods claimed and the method of McGill et al. are not in the same filed of endeavor, since in the claimed invention is drawn to hybridization of genomic DNA target to immobilized nucleic acid probes which are clones that represent all of the genome, whereas the field of endeavor of McGill et al. was comparing the amplification of one gene at one arm of one chromosome. Finally, Applicants argue that McGill is "not reasonably pertinent to the particular problems of the invention", since they teach probes which hybridize to metaphase chromosome spreads, but not to CGH array.

First, it is all relative of what ones defines as the "field of endeavor". In the case of both Kallioniemi et al. and McGill et al. the goal is to detect gene amplification by hybridization of probes to large DNA targets. Therefore, both references are concerned with probe-target hybridization. In the case of Kallioniemi et al., the targets are vectors with large DNA fragments, i.e., 10 kb to 1MB, whereas in the case of McGill et al. the target is whole chromosome 8. Therefore, if hybridizing 20 bp probes would provide sufficient specificity and stability of hybridization to the whole chromosome, it would be obvious to use such probes for sub-chromosomal fragments of CGH array of Kallioniemi et al. Further, it is not clear why McGill et al. need to be pertinent to the problems presented by CGH hybridization, since no such problems are claimed. Finally, taking into account the fact that a 20 bp sequence appears every 1,099,511,627,776 bp, and the whole of human genome has about 3,000,000,000 bp, such short probe would indeed provide the specificity required not to cause problems associated with sequence overlap.

The rejection is maintained.

D) Regarding the rejections of claims 7, 8 and 10 under 35 U.S.C. 103(a) over Kallioniemi et al., McGill et al. in view of Anderson; rejection of claim 9 under 35 U.S.C. 103(a) over Kallioniemi et al., McGill et al., Anderson in view of Waggoner et al; and rejection of claim 11 under 35 U.S.C. 103(a) over Kallioniemi et al., McGil et al. in view of Ordahl et al. and Anderson, Applicants argue that since Kallioniemi et al. and McGill et al. cannot be combined to render claim 1 obvious for reasons cited above, these rejections are improper. The arguments concerning combination of Kallioniemi et al. and McGill et al. references were addressed above.

The rejections are maintained.